

PACKAGE LEAFLET: Information for the patient

KLORUR NATRIUMI

Solution for injection – 1000 mg / 10 ml (10%)

Solution for injection – 85 mg / 10 ml (0.85%)

Solution for infusion – 0.9%

(Sodium chloride)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Klorur natrium is and what it is used for
2. Before you take Klorur natrium
3. How to take Klorur natrium
4. Possible side effects
5. How to store Klorur natrium
6. Other information

1. WHAT KLORUR NATRIUMI IS AND WHAT IT IS USED FOR

Klorur natrium contains the active substance sodium chloride. It is part of the large group of electrolytes.

Klorur natrium is used in the management of deficiencies of sodium and chloride ions in severe loss of salts.

Sodium chloride solutions are also used as a source for sodium, chloride and water for hydration. The solution 1000 mg / 10 ml (10%) is hyperosmotic.

2. BEFORE YOU TAKE KLORUR NATRIUMI

Do not take Klorur natrium:

- in case of hyperhydration;
- in severe renal failure;
- if you are hypersensitive (allergic) to any of the excipients of the drug, since allergic reactions may happen;
- in cases of hypernatraemia, hyperchloraemia;
- in cases when the use of sodium or chloride can be clinically harmful.

Take special care with Klorur natrium

Talk to your doctor or pharmacist before taking Klorur natrium.

Great quantities of sodium chloride, taken by any route of administration, can cause hypokalaemia and acidosis.

The solution of sodium chloride should be used with caution in patients with renal impairment, heart failure, hypertension, peripheral or pulmonary oedema, pre-eclampsia, hepatic cirrhosis or other conditions associated with sodium retention.

It should be used with caution in children and elderly people.

The solution with a concentration of sodium chloride greater than 0.9% (hypertonic solution) should be used with caution, controlled velocity and only when it is clearly indicated.

In patients who take corticosteroids or corticotropics, sodium chloride should be used with great caution.

It is recommended to control during infusion the fluid and electrolytes balance, plasmatic osmolarity and acid-basic balance.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription.

To minimise the risk of possible incompatibilities of sodium chloride solution for infusion when mixed with other solutions, the final mixture should be carefully observed prior to injection and periodically during it, if any turbulence or precipitation is formed.

It is of special importance to inform your doctor if you are treated with:

- corticosteroids, since they are associated with sodium and water retention, hence extreme caution is required if corticosteroids and sodium salts are administered simultaneously;
- glucose and fructose for the adjustment of electrolytes level;
- mannitol and sodium acetate in diuretic solutions, in cases of surgery of the cataract, in renal impairment;
- calcium chloride and potassium chloride to treat digestion disturbances;
- sodium bicarbonate in diabetic coma;
- potassium chloride, magnesium chloride during heart surgery;
- sodium sulphate, magnesium sulphate, potassium sulphate and potassium chloride in the treatment of constipation.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before taking this medicine.

Special care is required in women suffering from preeclampsia.

This medicine can be used during pregnancy and breastfeeding only under medical control.

Driving and using machines

This medicinal product does not affect the ability to drive or to use machines.

3. HOW TO TAKE KLORUR NATRIUMI

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The injectable solution of sodium chloride is administered parenterally (intravenously). For an adult, the daily requirements for Na^+ and Cl^- can be fulfilled by taking 1 L solution for infusion of sodium chloride 0.9% (154 milliequivalent sodium and 154 milliequivalent chloride).

If you take more Klorur natriumi than you should

If you take more Klorur natriumi than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.

The adverse effects which may happen from the overdosage of Klorur natriumi are the most serious effects of hypernatraemia, such as: brain dehydration, which may cause somnolence, confusion that progresses in convulsions, coma, respiratory failure and death.

If you forget to take Klorur natriumi

Ask your doctor or pharmacist for advice if you forget to take Klorur natriumi.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Klorur natriumi can cause side effects, although not everybody gets them.

Injection of high dosages can cause:

- sodium accumulation (hypernatraemia) and oedemas;
- acidosis (accumulation of chloride ions).

Side effects that may occur during intravenous use: hypervolemia, hypotension, chills, fever, local reactions, localized pain, paresthesia, skin reactions, tremor, vascular irritation, venous thrombosis, infection at the site of administration.

5. HOW TO STORE KLORUR NATRIUMI

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging.

Do not store above 25°C!

6. OTHER INFORMATION

What Klorur natriumi 1000 mg / 10 ml (10%) solution for injection contains

The active substance is Sodium chloride.

Each 10 ml ampoule contains 1000 mg sodium chloride.

The excipient is water for injections.

What Klorur natriumi 85 mg / 10 ml (0.85%) solution for injection contains

The active substance is Sodium chloride.

Each 10 ml ampoule contains 85 mg sodium chloride.

The excipient is water for injections.

What Klorur natriumi 0.9% solution for infusion glass bottles contain

The active substance is Sodium chloride.

1 ml solution for infusion contains 9 mg sodium chloride.

The excipient is water for injections.

What Klorur natriumi 0.9% solution for infusion plastic bags contain

The active substance is Sodium chloride.

1 ml solution for infusion contains 9 mg sodium chloride.

The excipients are sodium hydroxide and water for injections.

Contents of the pack

Klorur natriumi solution for injection is available in boxes of 10 ampoules.

Klorur natriumi solution for infusion is available in glass bottles of 100 ml, 250 ml, 500 ml and in plastic bags of 100 ml, 250 ml, 500 ml.

Marketing Authorisation Holder (MAH) and Manufacturer

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